REMARKS

Rejection of Claims and Traversal Thereof

In the February 1, 2010 Office Action:

claims 27, 30-32, 34, 35 and 37 were rejected under 35 U.S.C. §112, second paragraph;

claims 27, 30-31 and 34 were rejected under 35 U.S.C. §102(e) as being anticipated by Bachmann, et al. (US Publication 2003/0099668).

These rejections are hereby traversed and reconsideration of the patentability of the pending claims is therefore requested in light of the following remarks.

Rejection under 35 U.S.C. §112, second paragraph

Claims 27, 30-32, 34, 35 and 37 were rejected under 35 U.S.C. §112, second paragraph for being indefinite. Applicants have amended the claims thereby obviating this rejection and request the withdrawal of same.

Rejection under 35 U.S.C. §102(e)

Claims 27, 30-31 and 34 were rejected under 35 U.S.C. §102(e) as being anticipated by Bachmann, et al. (US Publication 2003/0099668). Applicants submit that the cited reference does not anticipate the presently claimed invention.

Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, **arranged as in the claim.** *Lindermann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984) The Bachmann reference does not meet this standard.

The present invention includes the following elements

A generic construct comprising:

1. at least one nucleotide sequence encoding at least one viral coat protein for expression in the host organism wherein the host organism is selected from the group consisting of yeast, bacteria, algae, fish or crustacean

2. a first exogenous sequence encodes for an antigenic or allergenic protein effective in the target animal;

3. a second exogenous sequence encodes for a tissue-targeting protein that has binding affinity for a receptor on a stomach or intestinal cell wall of the target animal.

4. wherein both the antigenic or allergenic protein and tissue-targeting protein, when expressed in the host organism, are displayed on the surface of the expressed viral coat protein.

It is very important to recognize that once the viral coat protein is expressed in the host organism, the viral coat protein along with the two surface proteins is administered orally to the target animal. Importantly, the targeting **protein that is targeted to a cell wall in the stomach or intestine of the target animal acts as a homing device to insure that the antigen is delivered to the gastrointestinal tissue. Figure 1, shown below, visually shows the delivery of the VLP to the cell wall.**

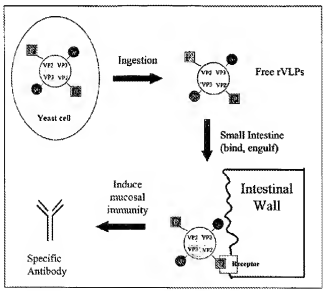

FIGURE 1

The prior art does not, in any way, disclose, teach or suggest such elements.

Applicants agree that the Bachmann reference does teach the use of a surface antigen, however, the other surface protein is not a targeting protein but instead acts as an adjuvant or an immunostimulatory molecule. The Office has made reference to several sections of the Bachmann reference but none of these sections explicitly or implicitly discloses the use of a targeting protein that has affinity for a surface receptor found in either stomach or intestinal tissue.

Paragraph 29 of Bachmann was cited by the Office, wherein the Bachmann invention is described as a virus like particle with an immunostimulatory nucleic acid and antigen wherein the immunostimulatory nucleic acid and antigen are fused to the VLP, as shown below:

> **[0029]** In a first embodiment, the invention provides a composition for enhancing an immune response in an animal comprising a virus-like particle and an immunostimulatory substance, preferably an immunostimulatory nucleic acid, an even more preferably an unmethylated CpG-containing oligonucleotide, where the substance, nucleic acid or oligonucleotide is coupled, fused, or otherwise attached to or enclosed by, i.e., bound, to the virus-like particle. In another embodiment, the composition further comprises an antigen bound to the virus-like particle.

The definition of immunostimulatory substance is explained in paragraph 131, as recreated below:

> **[0131]** Immunostimulatory substance: As used herein, the term "immunostimulatory substance" refers to a substance capable of inducing and/or enhancing an immune response. Immunostimulatory substances, as used herein, include, but are not limited to, toll-like receptor activing substances and substances inducing cytokine secretion. Toll-like receptor activating substances include, but are not limited to, immunostimulatory nucleic acids, peptidoglycans, lipopolysaccharides, lipoteichonic acids, imidazoquinoline compounds, flagellins, lipoproteins, and immunostimulatory organic substances such as taxol.

Clearly, this description of immunostimulatory substance does not provide any guidance for a targeting protein that is directed to surface tissue of the stomach or intestinal tract.

The Office makes further reference to the "toll-like receptor activating substance and toll like receptors as described in paragraph 231, recreated below:

> [**0231**] In another preferred embodiment of the invention molecules that active toll-like receptors (TLR) are enclosed. Ten human toll-like receptors are known uptodate. They are activated by a variety of ligands. TLR2 is activated by peptidoglycans, lipoproteins, lipoteichonic acid and Zymosan; TLR3 is activated by double-stranded RNA such as poly (I:C); TLR4 is activated by lipopolysaccharide, lipoteichoic acids and taxol; TLR5 is activated by bacterial flagella, especially the flagellin protein; TLR6 is activated by peptidoglycans, TLR7 is activated by imiquimoid acid and imidazoquinoline compounds, such as R418 and TLR9 is activated by bacterial DNA, in particular CpG DNA. Ligands for TLR1, TLR8 and TLR10 are not known so far. However, recent reports indicate that same receptors can react with different ligands and that further receptors are present. The above list of ligands is not exhaustive and further ligands are within the knowledge of the person skilled in the art.

Importantly, there are numerous TLRs recited in this paragraph with absolutely no guidance regarding the importance of the location of such receptors. Toll like receptors are a class of proteins that play a key role in the innate immune system, however, the majority of these cited receptors are expressed on a multiplicity of cell surfaces or cell compartments including, monocytes, dendritic cells, B lympocytes, plasma cells, mast cell, liver cells, kidney cells, bladder cells, endothelium, neurons, astrocytes and intestine cells. The cited reference teaches a multiplicity of different immunostimulatory substance and in fact merely discloses a broad genus of immunostimulatory substances with no guidance regarding the need for a targeting protein that is directed to stomach or intestine tissue of the target animal.

Clearly there can be no anticipation where the reference is so broad that the likelihood of arriving at the claimed composition would be the same as discovering the combination of a safe by an inspection of its dials, *Ex parte Garvey*, 41 USPQ 583 (POBA 1939). Nor is anticipation made out by hindsight selection based on an applicants' disclosure of variable of a broad generic disclosure (See *In re Ruschig et al.* 145 USPQ 274 (CCPA 1965)). Thus, the Bachmann reference does not in any way disclose, teach or suggest applicants' claimed invention.

The Bachmann reference provides a choice between multiple immunostimulatory substances, only one of which would be considered an expressed protein that may have affinity for a gastrointestinal

receptor. It is possible, by some serendipitous event that a receptor may be activated in the gastrointestinal tract by the Bachmann invention but clearly this would not happen each and every time. Further, the Office cannot imply that binding in the gastrointestinal tract inherently happens because inherency cannot be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *In re Oelrich*, 212 USPQ 323 (CCPA 1981). Instead, it must consistently occur each and every time, which is necessary under case law to prove inherency.

Thus, the chance of such a binding is so uncertain as to beg the question of whether the Bachmann reference meets the requirements of an anticipatory reference. It is well established as a matter of law that if a reference can be interpreted so that it may or may not constitute an anticipation of an applicant's claim, an anticipation rejection under 35 U.S.C. §102 based on the reference is improper (*In re Hughes*, 145 USPQ 467 (CCPA 1965)). This is the current situation, and as such, Bachmann does not support an anticipation rejection.

The Office makes further reference to paragraphs [0241] to [0260] and Example 6. However, none of these sections provides any additional guidance to go in the direction of applicants' claimed invention.

Accordingly, claims 27, 30, 31 and 34 patentably distinguish over Backmann. Withdrawal of the §102 rejection therefore is required.

Rejoining of Withdrawn Claims

Applicants request that method claims 42 to 47 be rejoined when the product claims are found allowable.

Fees payable

No fees are due for entry of this amendment, however, if a fee is found due the Commissioner is hereby authorized to charge any deficiencies, or reimburse any over-charges, to Deposit Account No. 13-4365 of Moore & Van Allen, PLLC.

Conclusion

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Blumel reconsider the patentability of the pending in light of the distinguishing remarks herein, and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Blumel is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,

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